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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,628	06/12/2002	Jerrold Rosenbaum	00786/376002	7156

21559 7590 07/15/2003

CLARK & ELBING LLP  
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BOSTON, MA 02110

EXAMINER

JONES, DWAYNE C

ART UNIT PAPER NUMBER

1614

DATE MAILED: 07/15/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/088,628

Applicant(s)

ROSENBAUM, JERROLD

Examiner

Dwayne C Jones

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-7, and 10-14 is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9 and 15-20 is/are rejected.
- 7) ☐ Claim(s) 21-23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other:

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-23 are pending.
2. Claims 1-4, 8, 9, and 15-20 are rejected.
3. Claims 21-23 are objected.
4. Claims 5-7, and 10-14 are allowed.

### ***Response to Arguments***

5. Applicant's arguments filed February 21, 2003 have been fully considered but they are not persuasive. Applicant argues the following points. Applicant argues that Caine et al. and Kutter et al. do not teach of the instant claimed pharmaceutical ranges. Next, applicant alleges that Cain et al. is only directed to experiments performed on rats and does not disclose the administration of pramipexole to humans.

6. Applicant argues that Caine et al. and Kutter et al. do not teach of the instant claimed pharmaceutical ranges. It is well within the skill level of the artisan to determine therapeutic dosage amounts as well as modes and methods of administration in order to determine optimum amounts of the active agent that afford the maximum effect of the active agent, such as pramipexole. Clearly, it would have been obvious to one having ordinary skill in the art to determine optimum amounts and modes and methods of administration, such as nasal administration, to a patient in need thereof for the purpose of delivering the optimum therapeutic amounts.

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7. Next, applicant alleges that Cain et al. is only directed to experiments performed on rats and does not disclose the administration of pramipexole to humans. The entire prior art reference of Cain et al. is directed to the treatment of cocaine abuse and dependence in humans not in other animals. The examples provided by Cain et al. simply demonstrate that the administration of pramipexole to a mammal is effective in the treatment of drug abuse, in particular cocaine abuse. Since it is well known in the art that various types of animal models are recognized as screening procedures with clear relevance to humans the skilled artisan would have been motivated to apply the rat models to other mammals. The skilled artisan would have been motivated to utilize the teachings of Cain et al. and apply these teachings and showings to other mammals, namely humans.

#### ***Claim Objections***

8. Claims 21-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-4, 8, 9, and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caine et al. Caine et al. teach that the administration of pramipexole decreased the self-administration of cocaine, (see abstract and page 2377). The instant method only differs in the specific range of dosages and the modes of administration. The determination of a dosage, modes and methods of administration having the optimum therapeutic index is well within the purview of the one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug. Accordingly, the Caine et al. reference makes obvious the instant invention.

12. Claims 1-4, 8, 9, and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kutter et al. Kutter et al. teach that the dopamine agonist of SND 919, which is also known as pramipexole, is known in the art to be effective in treatment of drug dependence that is mediated by dopamine release. In addition, Kutter et al. teach that this is accomplished by diminishing the reinforcement of drug consumption resulting from dopamine release in the brain centers and the euphoric inner enhanced reward with the administration of pramipexole, (see abstract). It is well within the skill

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level of the artisan to determine therapeutic dosage amounts as well as modes and methods of administration in order to determine optimum amounts of the active agent that afford the maximum effect of the active agent, such as pramipexole. Clearly, it would have been obvious to one having ordinary skill in the art to determine optimum amounts and modes and methods of administration, such as nasal administration, to a patient in need thereof for the purpose of delivering the optimum therapeutic amounts.

***Allowable Subject Matter***

13. Claims 5-7 and 10-14 allowed.

***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

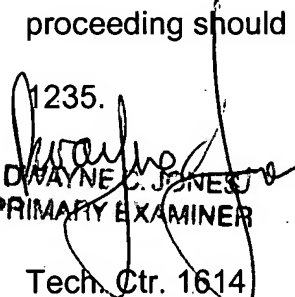
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.

  
DWAYNE C. JONES  
PRIMARY EXAMINER

Tech. Ctr. 1614  
July 13, 2003